

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LIXIAO WANG and DONALD J. FOURNIER

Appeal No. 2000-0793
Application No. 08/685,338

REMAND TO EXAMINER

MAILED

SEP 27 2000

**PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES**

Before CALVERT, COHEN and ABRAMS, Administrative Patent Judges.
CALVERT, Administrative Patent Judge.

REMAND TO THE EXAMINER
PURSUANT TO 37 CFR 1.196(e)

This is an appeal from the final rejection of claims 11 to 17 and 35 to 47, all the claims remaining in the application.

The claims on appeal are drawn to a balloon for a medical device and a method of treating a gastrointestinal lesion, and are reproduced in part 9 of appellants' brief.

The references applied in the final rejection are:

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|----------------------------|-----------|---------------|
| Cohen et al. (Cohen) | 5,167,239 | Dec. 01, 1992 |
| Kaneko et al. (Kaneko) | 5,344,400 | Sep. 06, 1994 |
| - Wang et al. (Wang) | 5,348,538 | Sep. 20, 1994 |
| Anderson et al. (Anderson) | 5,500,180 | Mar. 19, 1996 |

The appealed claims stand finally rejected on the following grounds:

- (1) Claim 11, anticipated by Anderson, under 35 U.S.C. § 102(e);
- (2) Claims 12 to 17 and 35 to 47, unpatentable under 35 U.S.C. § 103(a) over Anderson alone, or in view of Kaneko (claim 43) or Cohen (claims 46 and 47).

(A) Claim 11 is a product-by-process claim, which reads in part:

11. A balloon for a medical device made by the method of:

forming a balloon for a medical device, wherein a tubing of a thermoplastic polymer material is radially expanded . . . to form the balloon at a first diameter, the thermoplastic polymer material being a block copolymer material and the method including the further step of annealing the balloon . . .

The examiner finally rejected claim 11 as being anticipated by Anderson because (Answer, page 5):

Anderson et al. discloses a thermoplastic polymer material balloon, where the thermoplastic polymer material is a block copolymer material.

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The examiner further states at pages 7 and 8 of the Answer that this product-by-process claim is unpatentable because the claimed product is the same as that of Anderson, even though it is made by a different process, citing In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985), and MPEP §§ 2113 and 2173.05(p).

A prima facie case of unpatentability of a product-by-process claim is made out when the prior art discloses a product which reasonably appears to be either identical with (§ 102) or only slightly different than (§ 103) the claimed product. In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). In the present case, we do not consider the mere fact that Anderson discloses a medical device balloon made of a thermoplastic block copolymer is sufficient to establish that claim 11 is, prima facie, anticipated, as the examiner seems to believe. In view of the fact that the claimed balloon is not made by the same process as that disclosed by Anderson, it is incumbent on the examiner to provide a sound basis for concluding that the claimed product and that of Anderson are the same.¹

¹For example, as described in In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), the examiner in In re Thorpe, supra, made out a prima facie case "based on similarity of reactants, reaction conditions and properties."

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The application is accordingly remanded to the examiner to provide a prima facie basis for the rejection of claim 11 as being anticipated by Anderson, as well as for the obviousness rejection of dependent claims 12 to 17, dependent thereon.

(B) Claim 35, which may be taken as exemplary of independent claims 35 to 38 and 50, reads:

35. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 20 atmospheres, a diameter at 3 atmospheres of from about 1.5 to about 3.0 mm, and a diameter growth of at least 0.5 mm over the range of 3-12 atm.

The examiner has not separately considered the various parameters recited in these claims, as well as those recited in claims 12 to 17, 39, 41, 44 and 45, but merely broadly states that (Answer, page 6):

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Anderson et al. by providing to [sic] his balloon with a different variation of inflation pressure[s] and diameter[s] by varying and controlling the balloon expansion and heating process as evidenced by Anderson et al. at [sic: in] the process [sic] of making such balloon.

We note initially that Anderson may well disclose several of the parameters recited in these claims; for example, it discloses balloons having burst pressures of greater than 20 atmospheres with a nominal diameter of 3.0 mm in Examples 3 and 4. Also, the

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"distensibility" characteristic disclosed by Anderson (col. 3, line 64, to col. 4, line 9) would appear to be closely related to the diameter growth or average compliance recited in these claims.²

In any event, a conclusion of obviousness must rest on a factual basis, In re GPAC, Inc., 57 F.3d 1573, 1582, 35 USPQ2d 1116, 1123 (Fed. Cir. 1995), and even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). In order to make out a prima facie case of obviousness as to the claims in which specific numerical figures are recited, the examiner should analyze the disclosure of Anderson to determine which if any of those figures are disclosed by Anderson, and as to those that are not, should specify what disclosure in Anderson would have suggested to one of ordinary skill the particular claimed figures. (For example, would Anderson's disclosure at col. 2, lines 57 to 67, have suggested the various balloon diameters claimed ?).

²We do not find a definition of "compliance" in the application. Our understanding of the meaning of this term is derived from Patent No. 5,348,538, referred to on page 12, line 14 of the specification.

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The application is therefore remanded to the examiner for this further purpose.

The examiner's response to items (A) and (B) above should be contained in a Supplemental Examiner's Answer, in response to which appellants may file a Supplemental Reply Brief within the two month period set by 37 CFR § 1.193(b)(1).

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (Rev. 1, Feb. 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED



IAN A. CALVERT)
Administrative Patent Judge)



IRWIN CHARLES COHEN)
Administrative Patent Judge)



NEAL E. ABRAMS)
Administrative Patent Judge)

BOARD OF PATENT
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dr/vsh

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ROUTING FOR DECISIONS OF BOARD OF APPEALS

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| QAS | Initials <u><i>[Signature]</i></u> | date <u>10/17/00</u> |
| Director's Secretary | <u><i>CL</i></u> | <u>10/17/00</u> |
| Director | <u><i>[Signature]</i></u> | <u>3/21/01</u> |
| SPE | <u><i>[Signature]</i></u> | <u>1/31/01</u> |
| Examiner | <u><i>CR</i></u> | |

| Date of Decision | Serial Number | Examiner | Art Unit | Affirmed | Reversed | Aff'd-in-part | Remand |
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| 9/27/00 | 25/685338 | Rodriguez | 3763 | | | | <input checked="" type="checkbox"/> |
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